EXHIBIT 3

PRIVILEGED AND CONFIDENTIAL
ATTORNEY WORK-PRODUCT

Lee-Jen Wei, Ph.D.
Professor of Biostatistics
Harvard University

Report on Statistical Analysis of Use of Dietary and Occupational Studies to Infer Relationship Between NDMA and NDEA Impurities in Valsartan and Cancer

A. Introduction

1. This report is offered pursuant to Rule 26 of the Federal Rules of Civil Procedure. Each of the opinions[1] I have offered in this report is given to a reasonable degree of scientific certainty and is based on scientific methods and procedures, the materials I have reviewed in connection with this litigation, as well as my education, training, knowledge, and experience. I reserve the right to supplement this list, as well as to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, and any opinions offered by Plaintiffs' experts at their depositions or at trial.

[1] This report contains my opinions applicable to questions of general causation only. This report is not intended to be an exhaustive recitation of all of my opinions in this litigation, and I expressly reserve the right to amend or supplement this report to offer additional opinions, including opinions on liability, specific causation, damages, or other defenses, at the appropriate stage of litigation.

2. Citations to specific reference material are also offered in this report, where I believe it necessary to cite a specific source. Otherwise, my opinions are derived from a combination of reference sources and my own scientific knowledge. This report is not meant to be an exhaustive recitation of all of my opinions as I understand my opinions will be more fully explored at my deposition. My curriculum vitae, detailing my education, experience, and list of the publications I have authored, is attached to this report as Exhibit A.

3. A list of materials that I considered in rendering the opinions offered in this report is attached as Exhibit B. Because I have reviewed ample medical, regulatory, and scientific literature over my continued education in my field of expertise, it is not possible to list all of the material informing my opinions. I am, however, attaching a list of references that I have reviewed in Exhibit B. By including literature on this list, it does not imply that I place any particular emphasis on the reference or that I agree with all of the content in any particular publication.

4. At the time of trial, I may use other records or graphics to assist with the illustration of my opinions. I reserve the right to amend and further supplement my opinions based on additional material provided to me after the date of this report.

5. I may use at trial any exhibits as a summary or in support of all of my opinions including: (1) any of the materials, or excerpts identified in this report and attachments, including materials considered list; (2) excerpts from scientific articles or learned treatises; (3) demonstrative models; (4) exhibits used by the plaintiff's experts, or other witnesses; (5) the individual plaintiff's records; and (6) any exhibit used in or identified at any deposition take in this Litigation. If further data becomes available, I will be happy to review it and consider whether to modify any portion of these opinions.
6. I have been compensated at the rate of $500 per hour for my work on this matter. I have no conflicts of interest to disclose.
7. I have testified as an expert witness at deposition in one matter in the past four years: *In re Taxotere (Docetaxel) Products Liability Litigation*, MDL No. 2740 (E.D. La.).

B. Qualifications

8. I received a Ph.D. in Statistics in 1975 from the University of Wisconsin. I have been a tenured professor of biostatistics at Harvard University since 1991 and was a professor of biostatistical science and computational biology at Dana-Farber Cancer Institute, Harvard Medical School between 1997 and 2012. I was the scientific director for the Program of

Quantitative Sciences for Pharmaceutical Medicine and the co-director of the bioinformatics core at Harvard School of Public Health from 2003 to 2007. From 2003 to 2004, I served as the acting chair of the department of biostatistics at Harvard University. I was a tenured full professor of biostatistics and statistics at University of Wisconsin, University of Michigan, and George Washington University from 1982 to 1991.

9. Throughout my career, I have been intimately involved in the design, monitoring, and analysis of clinical studies, including for pharmaceuticals. I have served on numerous Data and Safety Monitoring Boards for clinical trials and have extensive experience in the evaluation of efficacy and safety data from clinical studies. I have long been actively involved in clinical research and development of a number of novel quantitative methods for analyzing data readily applicable to clinical studies.

10. My scholarly research includes over 230 publications in peer-reviewed journals. I am responsible for developing numerous novel statistical methods for designing, monitoring, and analyzing clinical studies, survival analyses, and meta-analyses. Many of these methods have been included in the most commonly used statistical software packages such as SAS, S-plus, and R. I have served on the editorial boards of a number of

statistical journals and am an elected Fellow of the American Statistical Association and Institute of Mathematical Statistics. I was named "Statistician of the Year" in 2007 by the Boston Chapter of the American Statistical Association. In 2009, I received the Wilks Medal from the American Statistical Association, one of the most prestigious awards in the field of statistics, for outstanding contributions to clinical trial methodological research.

C. Assignment

11. I have been retained by Defendants to provide an expert opinion in the litigation styled *In re: Valsartan Products Liability Litigation*, MDL No. 2875 (D.N.J.). Specifically, I was asked by counsel for Defendants to review and assess the opinions presented by David Madigan, Ph.D. who submitted an expert report on behalf of the Plaintiffs analyzing the results from the dietary and occupational studies to infer potential risk of carcinogenicity of NDME or NDEA impurities in Valsartan, and to provide my own assessment of those issues.

D. Executive summary

12. I disagree with the opinions, analysis and conclusions in Dr. Madigan's report; we cannot justify extrapolating the results from the dietary and

occupational studies to the patient population who took the Valsartan containing NDMA.

13. To claim a potential cancer risk via the dose response profile for NDMA using a "statistical significance" criterion (p-value < 0.05) is strongly discouraged by the American Statistical Association. Such a statistical claim does not have a clear clinical interpretation.

14. Even with the above artificial criterion to claim there is a dose response profile, one needs to make multiple adjustments for the p-values. In Dr. Madigan's report, there were at least 152 comparisons. Thus, the threshold value to define the so-called "statistical significance" is 0.0003, not 0.05, for each individual statistic test. Most tests for which Dr. Madigan claimed to be "statistically significant" would not be significant anymore with this threshold.

15. All the studies cited by Dr. Madigan in the report are observational. The observational studies heavily depend on the validity of modeling for adjusting the baseline imbalance between two groups to be compared. If these model assumptions are not met, the conclusions can be misleading. Moreover, the analysis and design of those dietary and occupational studies cannot support a causal relationship of cancer and valsartan. At best, they serve as a hypothesis generating vehicle. Without further well-

conducted, observational studies, conclusions about the potential connection between NDMA impurities in Valsartan and cancer are unreliable.

16. Based on my assessment of the dietary and occupational studies assessing the risk of cancer from NDMA, these studies fail to demonstrate a risk of cancer from Valsartan.

E. Statistical Analysis and Issues of Comparative Observational Studies for Assessing Exposure Effects

17. Suppose that we are interested in the rate of occurrence of a certain clinical event (for example, cancer) among subjects exposed to NDMA or NDEA to their counterparts (control). In the first step, we take a sample from a population of subjects exposed and another sample from the population of subjects who were not exposed. Assuming that these samples are valid representatives of the two populations, quantitative/analytic methods can be used to determine whether the exposed group has higher, lower or similar event rate than that for the control group. Since we draw conclusions based on a subset of subjects, any qualitative or quantitative interpretation of the result (i.e., whether the rate is higher or not) is subject to sampling error. That is, the observed event rate may be higher (leading to a possible false positive finding) or

lower (leading to a possible false negative finding) than the true event rate in the population. An efficient statistical method for analyzing such data minimizes the chance of making these two types of errors. It is important to note that except for the exposure to NDMA or NDEA, the exposed subjects in the sample should be similar to the subjects in the non-exposed sample with respect to important observable or unobservable confounders. Any imbalance with respect to those factors can seriously obscure the analysis results and results in invalid conclusions on the exposure effects.

18. After we have determined how to draw a valid sample from the population of interest, one has to determine what clinical endpoints are most appropriate to quantify the exposure effect. For the present legal case, the endpoint is whether the subject had a certain type of cancer or the time to occurrence of cancer. Suppose that based on a sample of 100 patients at the end of study, four patients experienced such events. An obvious estimate of the event rate for the underlying population is 0.04 (or 4%). This is called a point estimate. However, this estimate is based on a sample of patients. The true event rate for the entire population may be more or less than 4%. Different studies generating different samples may find a different proportions of subjects with cancer. Therefore, when

observing results from a single sample, it is important to attach a level of confidence to the observed point estimate. This quantitative, scientific process is called "drawing or making inferences" about the true event rate. For comparing the exposed and control groups, in the report by Dr. Madigan, the 95% confidence interval, and the p-value (whether less or greater than 0.05) were utilized to claim the exposure effect would be "statistically significant," which was repeatedly used in the report.

19. Let me turn to the issues of comparing two groups of subjects, one having been exposed and the other being in the control. To make sure that two samples of subjects are comparable with respect to all potential confounders, we often rely on a randomized clinical trial setting. Such a clinical study yields a well-designed experiment that has the potential for generating reliable prospective data on safety. Such studies are conducted and monitored according to a pre-specified protocol, which details the exposure administered (e.g., form, dosage, frequency), the clinical or biological endpoints (e.g., lab value, patient's quality of life, time to remission, time to a toxicity event), the study patient population and other clinical and statistical considerations. The trial is usually randomized and blinded. Subjects are assigned randomly to one of the study arms and neither physicians nor patients are told whether the patient is receiving an

active exposure or a control. This avoids selection bias or other experimental bias. When appropriately designed, results from a well-conducted, randomized clinical trial are regarded as a gold standard in controlled settings to evaluate the efficacy and safety of an exposure.

20. For the present case, we cannot utilize such a gold standard approach to evaluate the exposure effect. Thus, observational studies were used for all the articles cited by Dr. Madigan. It is known that such observational studies have inherent issues in the valid assessment of the exposure since we cannot guarantee the comparability between two groups at the subjects' baseline factors. For example, most of the studies cited by Dr. Madigan compared the least and most exposed groups with respect to NDMA. It is not clear one can ensure that those groups are only different with respect the exposure levels, but not for other factors.

21. Even if we can claim we collected all the relevant patients' baseline factors, the modeling of the adjustments for those factors may be questionable since the standard lack of fit test for the model fitting does not provide clinically meaningful interpretation via a p-value of the test. For example, in a publication Dr. Madigan heavily cited in his report, Loh

et al.[2] claimed that dietary NDMA intake was significantly associated with increased cancer risk in men and women via Cox proportional regression adjusted for age, sex, BMI, cigarette smoking status, alcohol intake, energy intake, physical activity status, educational level, and menopausal status (in women). However, it is not clear a thorough model fitting assessment was conducted. If the Cox model does not fit the data well, it is known that the resulting hazard ratio does not have clinically meaningful interpretation (Uno et al. 2014[3]; Pak et al. 2017[4]; Tian et al. 2018[5]). For this situation, the conclusions of the study and inferences drawn by Dr. Madigan based on the study would be invalid and inherently unreliable.

22. As another example about the adequacy of modeling, in the paper by Zheng et al.,[6] multiple logistic regression models were utilized. It is not

[2] Loh, Y. H., Jakszyn, P., Luben, R. N., Mulligan, A. A., Mitrou, P. N., & Khaw, K. T. (2011). N-Nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)-Norfolk Study. Am J Clin Nutr, 93(5), 1053-1061. doi:10.3945/ajcn.111.012377.
[3] Uno et al. Moving Beyond the Hazard Ratio in Quantifying the Between-Group Difference in Survival Analysis, Journal of Clinical Oncology (2014) DOI: 10.1200/JCO.2014.55.2208.
[4] Pak, et al. Interpretability of Cancer Clinical Trial Results Using Restricted Mean Survival Time as an Alternative to the Hazard Ratio (2017) *JAMA Oncol*. Doi:10.1001/jamaoncol.2017.2797.
[5] L. Tian et al. Moving beyond the conventional stratified analysis to estimate an overall treatment efficacy with the data from a comparative randomized clinical study, (2018) Statistics in Medicine. DOI: 10.1002/sim.8015.
[6] Zheng, J., Stuff, J., Tang, H., Hassan, M. M., Daniel, C. R., & Li, D. (2019). Dietary N-nitroso compounds and risk of pancreatic cancer: results from a large case-control study. Carcinogenesis, 40(2), 254-262. doi:10.1093/carcin/bgy169.

clear if the model fits the data well. Again, a lack of fit test for model fitting is not informative since it only provides a p-value. A large p-value from a test of goodness of fit does not mean the model would fit the data well since the test might not have power. On the other hand, a large study may result in a small p-value and we reject the model, which may be a good approximation to the true one. Without such analysis, the conclusions of the study and inferences drawn by Dr. Madigan based on the study would be invalid and inherently unreliable.

23. Moreover, for the papers in meta-analysis cited by Dr. Madigan, it is not clear if the authors for the individual papers in the meta-analysis had carefully checked the adequacy of the models utilized in the analysis. Without such analysis, the conclusions of the meta-analysis and inferences drawn by Dr. Madigan based on the meta-analysis would be invalid and inherently unreliable.

24. In their paper, Hidajat et al. (2019)[7] stated that "To examine the probability of dying from specific causes in a cohort with nearly complete mortality (94.1%), competing risk survival analysis was used to model

[7] Hidajat, M., et al: Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow-up. Occup. Environ. Med. 76:250-258, 2019.

time to death either from specific cancers, a competing event (death by another cause) or censored due to attrition (such as through emigration)." Following the method by Fine and Gray, they further stated that "Subjects who experienced a competing event before the event of interest remain in the risk set and are weighted using the inverse probability of censoring weighting approach. This is in contrast to a standard Cox proportional hazard approach which would consider deaths from competing risks to be censored and would be removed from the risk set. Censoring competing events violates the assumption that censoring occurred at random and is independent from the risk of dying from the cause of death of interest, leading to a biased Kaplan-Meier estimator. Furthermore, within the context of competing risks, the interpretation of HRs from a standard Cox proportional hazard approach changes to the hazards of dying if no other deaths occurred, which is untenable in a cohort with 94.1% mortality rate. Subdistribution HRs (SHRs) are estimated using *stcrreg* in Stata V.15 and comparable in interpretation to proportional HRs in Cox models."

25. Unfortunately, using the subdistribution hazard ratio to quantify the group difference in the presence to competing risks has been criticized

(Zhao et al. 2018, JAMA-Cardiology[8]; McCaw et al. 2020, New England Journal of Medician[9]; McCaw et al. 2020, Annals of Internal Medicine[10]). Such hazard ratio has no clinical meaning. In fact, this issue was also cited by Fine and Gray (1999),[11] which was the method used by Hidajat et al in their report. Therefore, the results reported by Hidajat et al are difficult to interpret clinically. Alternative methods have been proposed in the above cited articles.

F. Extrapolation of the Results from the Diet or Occupation Studies to Infer the Exposure Issues for Valsartan Population

26. Based on the information available and the content of Dr. Madigan's report, we cannot use the results from diet or occupation studies to make an inference about the exposure effects for the population with valsartan. For example, from the meta-analysis by Song et al. regarding gastric cancer and NDMA consumption, the authors clearly stated that there was an obvious evidence of heterogeneity among studies involved, as

[8] Zhao L, Tian L, Claggett B, et al. Estimating treatment effect with clinical interpretation from a comparative clinical trial with an end point subject to competing risks. JAMA Cardiol (2018); 3: 357-8.
[9] McCaw, Zack, Kim, Dae and Lee-Jen Wei, Letter to the Editor for Remdesivir for the Treatment of Covid-19— Preliminary Report, New England Journal of Medicine (2020). DOI: 10.1056/NEJMc2022236.
[10] McCaw et al., How to Quantify and Interpret Treatment Effects in Comparative Clinical Studies of COVID-19, (2020) Ann Intern Medicine, doi:10.7326/M20-4044
[11] Fine JP, Gray RJ. A proportional hazards model for the subdistribution of a competing risk. J Am Stat Assoc (1999), 94:496–509.

demonstrated by their use of the random effects model to deal with heterogeneity. [12] That is, the study populations in the meta-analysis are quite different and the resulting risks vary drastically across studies. Some studies suggested no exposure effects at all. For instance, the study by Knekt et al.[13] On the other hand, the study by Larsson et al. indicated issues of potential cancer risk.[14] Therefore, even for the diet consumption studies, one cannot extrapolate the results from one study to another population even within the dietary research area. Using the results from non-valsartan studies to claim issues for potential carcinogenicity of low levels of an NDMA impurity in valsartan is not scientifically valid. Based on my assessment of the dietary and occupational studies assessing the risk of cancer from NDMA, these studies fail to demonstrate a risk of cancer from Valsartan.

[12] Song, P., Wu, L., & Guan, W. (2015). Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis. Nutrients, 7(12), 9872-9895. doi:10.3390/nu7125505.

[13] Knekt, P.; Jarvinen, R.; Dich, J.; Hakulinen, T. Risk of colorectal and other gastro-intestinal cancers after exposure to nitrate, nitrite and N-nitroso compounds: A follow-up study. Int. J. Cancer (1999), 80, 852–856.

[14] Larsson, S.C.; Bergkvist, L.; Wolk, A. Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women. Int. J. Cancer (2006), 119, 915–919.

G. Studies Directly Dealing with the Valsartan Impurities

27. Pottegård et al. conducted a Danish nationwide cohort study to investigate whether the use of N-nitrosodimethylamine (NDMA) contaminated valsartan products would increase the risk of cancer.[15] In the study, there were 5,150 Danish patients with no history of cancer, aged 40 years or older, and using valsartan on January 1, 2012, or initiating use between January 1, 2012 and June 30, 2017. The primary endpoint is the time to all cancers except non-melanoma skin cancer. The study used a Cox regression model with covariates adjustments. There were 3,625 participants contributed 7,344 person years classified as unexposed to NDMA, and 3,450 participants contributed 11,920 person years classified as ever exposed to NDMA.[16] There were 104 cancer outcomes among NDMA unexposed participants and 198 among exposed participants, the adjusted hazard ratio for overall cancer was 1.09 (95% confidence interval 0.85 to 1.41). Moreover, there was no evidence of a dose-response relation. As such, the study suggests that there is no evidence to justify valsartan with NDMA caused cancer. The proportional hazards

[15] Pottegård A, Kristensen KB, Ernst MT, Johansen NB, Quartarolo P, Hallas J. 2018. Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study. BMJ 362:k3851. doi:10.1136/bmj.k3851.
[16] *Id.*

assumption was tested using Schoenfeld residuals in the paper. Various sensitivity and supplementary analyses were also conducted for supporting the robustness of the results from the primary analysis. This type of studies are more reliable for assessing the exposure effect from valsartan with NDMA than the diet and occupational studies.

28. Gomm et al. conducted a study to investigate the same issue via German health insurance data.[17] There were 780,871 persons who had filled a prescription for valsartan between 2012 and 2017 included in the study. There was no evidence on an association between exposure to NDMA-contaminated valsartan and the overall risk of cancer. There were 10 different types of cancers explored in the study. Only for liver cancer, the hazard ratio is 1.16 with a 95% confidence interval of 1.03 to 1.3.[18] However, if we apply the multiple comparison adjustment with ten cancer categories via Bonferroni adjustment, the confidence level would be 99.5%, not 95%. Therefore, the resulting confidence interval will cover 1, which indicates that there is no evidence of the association between the exposure and the liver cancer.

[17] Gomm W, Röthlein C, Schüssel K, et al. 2021. N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer—A Longitudinal Cohort Study Based on German Health Insurance Data. Deutsches Ärzteblatt international 118 (Forthcoming). doi:10.3238/arztebl.m2021.0129. Online ahead of print.
[18] *Id.*

PRIVILEGED AND CONFIDENTIAL
ATTORNEY WORK-PRODUCT

H. Overuse of "statistical significance" via a p-value < 0.05 as a criterion to assess the exposure effects

29. Dr. Madigan repeatedly based his conclusions about the exposure effect solely on whether the p-value was less than 0.05 or not. But the overemphasis of using p=0.05 as the cutoff for "statistical significance" has been strongly criticized by experts in the field of statistics and the American Statistical Association ("ASA"). For this reason, the ASA (the most influential and the largest statistical professional society in the world), issued a formal statement in 2016 to strongly discourage using a threshold value of 0.05 or any other arbitrary value to claim a "significance" finding.[19] The statement also emphasized that the "p-value was never intended to be a substitute for scientific reasoning."[20]

[19] Ronald L. Wasserstein & Nicole A. Lazar (2016) The ASA Statement on *p*-Values: Context, Process, and Purpose, *The American Statistician*, 70:2, 129-133, DOI: 10.1080/00031305.2016.1154108.

[20] *Id.* ("Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold. Practices that reduce data analysis or scientific inference to mechanical "bright-line" rules (such as "$p < 0.05$") for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making. A conclusion does not immediately become "true" on one side of the divide and "false" on the other. Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis. Pragmatic considerations often require binary, "yes-no" decisions, but this does not mean that p-values alone can ensure that a decision is correct or incorrect. The widespread use of "statistical significance" (generally interpreted as "$p \leq 0.05$") as a license for making a claim of a scientific finding (or implied truth) leads to considerable distortion of the scientific process.").

30. Dr. Madigan's report repeatedly relies on a threshold value of 0.05 to claim the exposure effect on cancer risk without clinically and scientifically meaningful interpretations. Accordingly, Dr. Madigan's conclusions are not relevant to the subject matter of the present litigation.

I. Issue of using multiple statistical tests without adjustment

31. Even if we accept Dr. Madigan's criteria with a false positive rate of 0.05 as an arbitrary threshold value, this procedure was generally used to establish the so-called "statistical significance" of a result when testing a *single* clinical endpoint in a *single* study. This level can be very "liberal" (i.e., can result in statements of statistical significance when none exists) if *multiple* statistical tests and/or studies are examined simultaneously. In other words, making multiple comparisons would seriously inflate the overall "false positive" rate. For example, in the article by Zheng et al. cited in paragraph 13 of Dr. Madigan's report, in their Table 2, there were 24 comparisons for the trend tests. Using the 5% rule for claiming statistical significance to analyze simultaneously a large number of tests in a study will yield a high rate of false positive findings. Often, the overall false positive rate could be as high as 20% or more (that is, a very high chance of finding an exposure is not safe with respect to control, when, in fact, there is no difference between the two groups). This would lead to

wrong conclusions about the exposure effects. Inflated false positive rate issues have been extensively discussed, for example, in Friedman, Furberg and DeMets[21] when dealing with multiple testing or simultaneous inferences. For another article cited in Dr. Madigan's report (Goodman et al.) regarding the lung cancer, in their Table 1, there were 74 trend tests. For the comparisons for Q2, Q3 and Q4 vs Q1 (Sometimes, Dr. Madigan used the *first, second* and *third quantile*, I assume he meant quartiles) with respect to various degrees of exposures, there were 444 tests. For these cases, the false positive rates would be drastically increased and none of the comparisons would be "statistically significant."

32. A standard procedure to handle the multiple comparison issue is to use the Bonferroni adjustment. For example, if there are 50 different types of tests conducted, the total false positive rate is 5%, then for each individual test, we should use a false positive rate of 0.1% (5% divided by 50) to assess whether there is a potential signal on the safety concern. The corresponding confidence interval level should be 99.9% (100% - 0.1%). For the study by Goodman et al. The level of threshold value would be

[21] For details see Friedman, Furberg and DeMets, Fundamentals of Clinical Trials, Second Edition, Chapter 15; p. 215, Littleton, MA, 1985.

0.05/444 = 0.00011. That is, unless a p-value is less than 0.00011, one could not claim so called "statistical significance."

33. The problem of inflation of a Type I error (or false positive) rate becomes much worse when we examine the results of several independent clinical studies at the same time with a Type I error rate of 0.05 for each study. For example, suppose there are three independent studies which compare the exposure group with control. Suppose that we claim that there is a significant difference between these two groups when the p-value of any one of these three trials is less than 0.05. If we apply this decision rule, the total Type I error rate would be 14.3%; that is, even if there were no differences between the exposure and control with respect to cancer incidence, the chance of claiming either the exposed or control is harmful is more than 14.3%. This problem is compounded if we apply the same rule to a large number of studies. Therefore, when we analyze multiple studies and statistical test simultaneously, any conclusion of toxicity must be carefully interpreted due to the multiplicity of tests.

34. Since Dr. Madigan cited multiple studies with an extremely large number of statistical tests in his report, all the so-called "statistical significance" claims would not be valid using 0.05 as the threshold value for each test. In his report, from two tables presented for the dietary and occupational

studies, Dr. Madigan reported 152 test results and highlighted the "statistically significant" entries. With the multiple comparison adjustments, each test should use the critical value of 0.05/152 = 0.0003. It is not clear which entries in the tables of the occupational and diet studies would still be "statistically significant."

J. Errors and Inconsistency in Dr. Madigan's report

35. Dr. Madigan's report contains various errors. For example, regarding esophageal cancer, it stated that Cui et al. found an increased risk of such cancer risk associated with NDMA, the *hazard ratio* =1.18, and 95% CI (0.98, 1.41). In Cui paper, I cannot find such a claim with respect to hazard ratio. He then added the odds ratio results from Rogers et al. to Cui's. One cannot combine odds ratio with the hazard ratio (if Cui were using the hazard ratio as the summary measure). The odds ratio and hazard ratio are quite different summary measures for assessing the toxicity (Paragraph 12 in Dr. Madigan's report). One is using the binary outcome (yes or no for cancer) and the other using the time to occurrence of cancer.

36. Dr. Madigan added Loh's *hazard ratio* of 1.13 to Song's meta-analysis, but Song did not report hazard ratios in their article (Paragraph 10 in Dr. Madigan's report). It is not clear if we combine these two different

summary measures how to interpret such a combination and whether any conclusions inferred from this combination are valid.

K. Conclusions

37. In Paragraph #33 in the report, Dr. Madigan claimed that for NDMA, "statistically significant" increased gastric cancer risk arises at LCEs as low as 1,962 ug, the equivalent threshold for lung cancer is 4,303 ug, for esophageal cancer is 4,235 ug, and for rectal cancer is 3,343 ug. Based on the report by Dr. Madigan, those claims cannot be justified with the issues and concerns I raised in this report.

38. The same concern is applied to the claims in Paragraph #34 in Dr. Madigan's report. Moreover, those threshold values may not be transportable to the case for the contaminated valsartan without appropriate validations. Thus the risks of cancer discussed in Paragraphs 33 and 34 in Dr. Madigan's report are not scientifically justified. Based on my review of the studies discussed by Dr. Madigan the dietary and occupational studies and the NDMA levels referenced cannot be extrapolated to Valsartan with NDMA.

39. There is no statistical evidence based on studies cited by Dr. Madigan that the levels of NDMA or NDEA reported in valsartan can cause cancer. Based on my review of the studies referenced by Dr. Madigan and my

own review of his analysis, based on scientifically valid reasoning and methodology, I do not see any valid statistical support that Valsartan with NDMA or NDEA can cause cancer in patients.

Date: August 2, 2021

Lee-Jen Wei, Ph.D.

WEI

EXHIBIT A

CURRICULUM VITAE

LJ WEI

ADDRESS

Lee-Jen Wei
Department of Biostatistics Harvard University
677 Huntington Avenue
Boston, MA 02115
Phone: (617) 432-2826
E-mail address: wei@hsph.harvard.edu

EDUCATION

1970	B.S., Mathematics, Fu-Jen University, Taipei, Taiwan
1975	Ph.D., Statistics, University of Wisconsin, Madison

WORKING EXPERIENCE

2003-2004	Acting Chair Department of Biostatistics Harvard University
1997-present	Professor of Biostatical Science and Computational Biology Dana-Farber Cancer Institute
1991-present	Professor of Biostatistics Harvard University
1988-1991	Professor of Statistics and Human Oncology Associate Director of Biostatistics Center University of Wisconsin, Madison, Wisconsin
1986-1988	Professor of Biostatistics and Statistics University of Michigan; Director, Biostatistics Unit University of Michigan Cancer Center
1985-1986	Professor of Statistics George Washington University
1984-1985	Visiting Professor of Biostatistics Harvard University
1981-1984	Professor of Statistics George Washington University

1980-1981	Cancer Expert National Cancer Institute, NIH
1979-1981	Associate Professor of Statistics University of South Carolina
1975-1979	Assistant Professor of Statistics University of South Carolina

HONORS

2009	Wilks Memorial Award, American Statistical Association
2007	Mosteller Statistician of the Year (sponsored by Boston Chapter, American Statistical Association)
2001	Greenberg Distinguished Lectureship Univ. of North Carolina at Chapel Hill
1999	Distinguished Alumni Award, Fu Jen University
1993	Fellow, Institute of Mathematical Statistics
1991	A.M. (Honorary Degree), Harvard University
1988	Elected Member, International Statistical Institute
1986	Fellow, American Statistical Association
1987	Spiegelman Award for Outstanding Statistical Research in Public Health, American Public Health Association

EDITORIAL ACTIVITIES

1984-1991	Associate Editor, Journal of the American Statistical Association (Theory and Methods Section)
1993-1996	Associate Editor, Journal of the American Statistical Association (Theory and Methods Section)
2005-present	Associate Editor, Journal of the American Statistical Association (Theory and Methods Section)
1984-1988	Member of Editorial Board, Communications in Statistics (A)
1988-1996	Associate Editor, Statistica Sinica
1989-1993	Associate Editor, Biometrics
1990-2000	Associate Editor, Journal of Biopharmaceutical Statistics

PH.D. STUDENTS

Levint (1983) Nonparametric survival analysis for block designs.

C. Cowan (1984) The effect of misclassification on estimates from capture and recapture studies.

W. Johnson (1985) Combining dependent tests with incomplete repeated measurements.

S. Davis (1987) Nonparametric methods for analyzing incomplete non-decreasing repeated measurements.

Y. Lin (1989) Robust inference and goodness-of-fit tests for Cox's proportional hazards model.

J. Su (1990) Lack-of-fit tests for generalized linear models.

E. Lee (1991) Regression analysis for the correlated clustered failure time data.

J.S. Lin (1991) Analysis of multivariate survival data.

S.H. Jung (1992) Survival analysis with median regression models.

C. Cheng (1995) Transformation models for survival data Li Chen (1996) Analysis of correlated observations.

Jason Fine (1998) Statistical methods for competing risks data.

Cai (1999) Analysis of clustered failure time data.

L. Tian (2002) Regression analysis of time-varying coefficients models.

Y. Park (2004) Semi-parametric inferences for censored survival time data.

L. Leon (2005) Robust inference and model checking techniques for censored linear regression models (Co-advisor).

James Signorovitch (2007) Identifying informative biological markers in high-dimensional genomic data and clinical trials.

Brian Claggett (2012) Statistical methods for clinical trials with multiple outcomes, HIV surveillance, and nonparametric meta-analysis.

Florence Yong (2015) Quantitative methods for stratified medicine.

STATISTICAL METHOD RESEARCH PUBLICATIONS

1. Wei, L.J. (1977) "A class of designs for sequential clinical trials," Journal of the American Statistical Association, 72:382–386.

2. Padgett, W.J. and Wei, L.J. (1977) “Bayes estimation of reliability for the two-parameter lognormal distribution,” Communications in Statistics, A:443–447.

3. Wei, L.J. (1977) “A sequential searching scheme for an optimal dosage,” Australian Journal of Statistics, 18:163–171.

4. Wei, L.J. (1978) “The adaptive biased coin design for sequential experiments,” Annals of Statistics, 6:92–100.

5. Wei, L.J. (1978) “On the random allocation design for the control of se- lection bias,” Biometrika, 65:79–84.

6. Wei, L.J. (1978) “A class of treatment assignment rules for sequential experiments,” Communications in Statistics, A:285–295.

7. Wei, L.J. and Durham, S. (1978) “The randomized play-the-winner rule,” Journal of the American Statistical Association, 73:840–843.

8. Wei, L.J. (1978) “The application of an urn model in controlled clinical trials,” Journal of the American Statistical Association, 73:559–563.

9. Padgett, W.J. and Wei, L.J. (1978) “Lower bounds on reliability for the log-normal model and comparison with a classical lower confidence bound,” IEEE Transaction of Reliability, 161–165.

10. Wei, L.J. (1979) “The generalized Polya’s urn design for sequential experiments,” Annals of Statistics, 7:291–296.

11. Padgett, W.J. and Wei, L.J. (1980) “Estimation for the three-parameter inverse Gaussian distribution,” Communications in Statistics, A:129–137.

12. Spurrier, J. and Wei, L.J. (1980) “A test of the exponential parameter in the Type 1 censoring case,” Journal of the American Statistical Association, 75:405–409.

13. Padgett, W.J. and Wei, L.J. (1980) “Maximum likelihood estimation of a distribution function with monotone failure rate based on censored observations,” Biometrika, 67:470–474.

14. Wei, L.J. (1980) “A generalized Gehan and Gilbert test for paired observations which are subject to arbitrary right censorship,” Journal of the American Statistical Association, 75:634–637.

15. Padgett, W.J. and Wei, L.J. (1981) “A Bayesian nonparametric estimation of survival probability assuming increasing failure rate,” Communications in Statistics, A:49–63.

16. Wei, L.J. (1981) “Estimation of location difference for fragmentary samples,” Biometrika, 76:471–476.

17. Wei, L.J. (1981) “Asymptotic conservativeness and efficiency of Kruskal-Wallis test for K dependent samples,” Journal of the American Statistical Association, 76:1006–1009.

18. Wei, L.J. (1982) “Interval estimation of location differences with missing observations,” Biometrika, 69:249–251.

19. Wei, L.J. (1982) “Asymptotically distribution-free simultaneous confidence region of treatment differences in a randomized block design,” Journal of the Royal Statistical Society (B), 44:201–208.

20. Padgett, W.J. and Wei, L.J. (1982) “Estimation of the ratio of two parameters with censored observations,” Biometrika, 69:252–256.

21. Slud, E. and Wei, L.J. (1982) “Repeated significance test for censored observations with a modified Wilcoxon statistic,” Journal of the American Statistical Association, 77:861–869.

22. Padgett, W.J. and Wei, L.J. (1982) “A sequential test and interval estimation in time truncated life testing,” Sankhya A, 44:242–250.

23. Wei, L.J. and Gehan, E. (1983) “The Gehan-Gilbert Test.” The Encyclopedia of Statistical Sciences. Vol. 3, pp. 318–320. Edited by N. L. Johnson and S. Kotz. New York: Wiley.

24. Wei, L.J. (1983) “The Friedman’s urn model.” The Encyclopedia of Statistical Sciences. Vol. 3, p. 251. Edited by N. L. Johnson and S. Kotz. New York: Wiley.

25. Wei, L.J. and Gail, M. (1983) “Nonparametric estimation for a scale- change model with censored observations,” Journal of the American Statistical Association, 78:382–388.

26. Wei, L.J. (1983) “Tests for independence in the presence of missing values,” Australian Journal of Statistics, 24:85–90.

27. Smythe, R.T. and Wei, L.J. (1983) “Significance test with a restricted randomization design,” Biometrika, 70:496–500.

28. Wei, L.J. (1983) “Tests for interchangeability with incomplete paired observations,” Journal of the American Statistical Association, 78:725–729.

29. Wei, L.J. and Cowan, C. “Selection Bias.” The Encyclopedia of Statistical Sciences. Vol. VI. Edited by N. L. Johnson and S. Kotz. New York: Wiley.

30. Wei, L.J. and Byar, D. “Play-the-winner’s rule.” The Encyclopedia of Statistical Sciences. Vol. VI. Edited by N. L. Johnson and S. Kotz. New York: Wiley.

31. Padgett, W.J. and Wei, L.J. (1984) “Interval estimation after sequential testing based on the total time on tests,” Journal of Operations Research, 726–731.

32. Wei, L.J. and Lachin, J. (1984) “Nonparametric multivariate tests for in-complete observations,” Journal of the American Statistical Association, 79:653–661.

33. Wei, L.J. (1984) “Testing goodness-of-fit for proportional hazards model with censored observations,” Journal of the American Statistical Association, 79:649–652.

34. Wei, L.J. and Johnson, W. (1985) “Combining dependent tests with in- complete repeated measurements,” Biometrika, 72:359–364.

35. Wei, L.J. and Pee, D. (1985) "Distribution-free methods of estimating location difference with censored paired data," Journal of the American Statistical Association, 80:405–410.

36. Wei, L.J., Smythe, R., and Smith, R. (1986) "On restricted randomization rules in clinical trials," Annals of Statistics, 14:265–274.

37. Wei, L.J. (1987) "Two-sample problem with bivariate exchangeable observations," Journal of the Royal Statistical Society (B), 49:40–45.

38. Wei, L.J. and Knuiman, N.W. (1988) "A one-sided rank test for multivariate censored data," The Australian Journal of Statistics, 29:214–219.

39. Wei, L.J. and Stram, D. (1988) "Analyzing repeated measurements with possibly missing observations by modeling marginal distributions," Statistics in Medicine, 7:139–148.

40. Mehta, C.R., Patel, N., and Wei, L.J. (1988) "Constructing exact significance tests with restricted randomization rules," Biometrika, 75:295–302.

41. Stram, D., Wei, L.J., and Ware, J. (1988) "Analysis of repeated ordered categorical observations," Journal of the American Statistical Association, 83:631–637.

42. Wei, L.J. (1988) "Constructing exact two-sample permutational tests with the randomized play-the-winner rule," Biometrika, 75:603–606.

43. Lachin, J. and Wei, L.J. (1988) "Analysis of non-independent 2 2 tables with partially missing observations," Biometrics, 44:513–528.

44. Wei, L.J. and Lachin, J. (1988) "Properties of the urn randomization in clinical trials," Controlled Clinical Trials, 9:345–364.

45. Davis, C.S. and Wei, L.J. (1988) "Analysis of nondecreasing repeated measurements," Biometrics, 44:1005–1018.

46. Wei, L.J., Smythe, R.T., and Mehta, C.R. (1989) "Interval estimation with restricted randomization rules," Biometrika, 76:363–368.

47. Lin, D.Y. and Wei, L.J. (1989) "Discussion of 'Interim analysis: the repeated confidence interval approach,' by C. Jennison and B. W. Turnbull." Journal of the Royal Statistical Society (B), 51:347–348.

48. Lin, D.Y. and Wei, L.J. (1989) "Discussion of 'Investigating therapies of potentially great benefit: ECMO,' by J. Ware." Statistical Science, 4:324– 325.

49. Lin, D.Y. and Wei, L.J. (1989) "The robust inference for the Cox proportional hazards model," Journal of the American Statistical Association, 84:1074–1078.

50. Wei, L.J., Lin, D.Y., and Weissfeld, L. (1989) "Regression analysis of multivariate incomplete failure time data by modeling marginal distributions," Journal of the American Statistical Association, 84:1065–1073.

51. Wei, L.J., Smythe, R.T., Lin, D.Y., and Park, T.S. (1990) "Statistical inference with data-dependent treatment allocation rules," Journal of the American Statistical Association, 95:157–162.

52. Wei, L.J., Su, J., and Lachin, J. (1990) "Interim analyses with repeated measurements in a sequential clinical trial," Biometrika, 77:359–364.

53. Wei, L.J. (1990) "Comments on 'On inferences from Wei's biased coin design for clinical trials' by C. Begg," Biometrika, 77:476–477.

54. Wei, L.J., Ying, Z., and Lin, D.Y. (1990) "Linear regression analysis for censored observations based on rank tests," Biometrika, 77:845–851.

55. Lin, D.Y. and Wei, L.J. (1991) "A lack-of-fit test for a general Cox's regression model," Statistica Sinica, 1:1–17.

56. Su, J. and Wei, L.J. (1991) "A lack-of-fit test for the generalized linear model," Journal of the American Statistical Association, 86:420–426.

57. Lin, D.Y. and Wei, L.J. (1991) "Repeated confidence intervals for a scale change in a sequential survival study," Biometrics, 47:289–294.

58. Lin, J.S. and Wei, L.J. (1992) "Buckley-James procedures for failure time data," Biometrics, 48:679–681.

59. Wei, L.J. (1992) "Accelerated failure time model: a useful alternative to the Cox model in the analysis of survival data," Statistics in Medicine, 11:1871–1880.

60. Lin, J.S. and Wei, L.J. (1992) "Linear regression analysis for multivariate failure time observations," Journal of the American Statistical Association, 87:1091–1097.

61. Lin, D.Y. and Wei, L.J. (1992) "Comments on the paper 'A survey of exact inference for contingency tables' by A. Agresti," Statistical Science, 7:166–167.

62. Ying, Z., Lin. J.S., and Wei, L.J. (1992) "Prediction of survival probability based on a linear regression model," Biometrika, 79:205–209.

63. Lee, E., Wei, L.J., and Amato, D. (1992) "Cox-type regression analysis for large numbers of small groups of correlated failure time observations," in Survival Analysis: State of the Art, NATO ASI Series, Vol. 211, edited by J.P. Klein and P.K. Goel.

64. Lin, D.Y., Wei, L.J., and DeMets, D.L. (1991) "Exact statistical inference for group sequential trials," Biometrics, 47:1399–1408.

65. Lee, E., Wei, L.J., and Ying, Z. (1993) "Linear regression analysis for highly stratified failure time data," Journal of the American Statistical Association, 88:557–565.

66. Su, John Q. and Wei, L.J. (1993) "Nonparametric estimation for the difference or ratio of median failure times," Biometrics, 49:603–607.

67. Lin, D.Y., Wei, L.J., and Ying, Z. (1993) "Checking the Cox model with cumulative sums of martingale residuals," Biometrika, 80:557–572.

68. Ying, Z., Jung, S.H., and Wei, L.J. (1995) "Median regression analysis with censored data," Journal of the American Statistical Association, 90:178– 184.

69. Keaney, K.M., and Wei, L.J. (1994) “Interim analysis based on median survival times,” Biometrika, 81:279–286.

70. Parzen, M.I., Wei, L.J., and Ying, Z. (1994) “A resampling method based on pivotal estimating functions,” Biometrika, 81:341–350.

71. Lin, D.Y., Fleming, T.R., and Wei, L.J. (1994) “Confidence bands for survival curves under the proportional hazards model,” Biometrika, 81:73– 81.

72. Ying, Z. and Wei, L.J. (1994) “The Kaplan-Meier estimate for dependent failure time observations,” Journal of Multivariate Analysis, 50:17–29.

73. Lin, D.Y., Robins, J.M. and Wei, L.J. (1996) “Comparing two failure time distributions in the presence of dependence censoring,” Biometrika, 83:381–393.

74. Cheng, S.C., Wei, L.J. and Ying, Z. (1995) “Analysis of transformation models with censoring data,” Biometrika, 82:835–845.

75. Yao, Q. and Wei, L.J. (1996) “Play the winners for phase II and III clinical trials,” Statistics in Medicine, 15:2413–2423.

76. Wei, L.J. and Glidden, D. (1996) “An overview of statistical methods for multiple event times data in clinical trials,” Statistics in Medicine, 16:833– 839.

77. Rossini, A., Wei, L.J. and Z. Ying (1996) “Checking the adequacy of two sample location shift model,” Life Data Analysis, 2:145–157.

78. Zackin R. and Wei, L.J. (1997) “Analysis of repeated virological measurements based on cell dilution assays,” Statistics in Medicine, 16:571–582.

79. Cheng, C.S., Wei, L.J. and Ying, Z. (1997) “Predicting survival probabilities with semi-parametric transformation models,” Journal of the Ameri- can Statistical Association, 92:227–235.

80. Parzen, M., Wei, L.J., and Ying, Z. (1997) “Simultaneous confidence intervals for the difference of two survival functions,” Scandinavian Journal of Statistics, 24.

81. Yao, Q., Wei, L.J. and Hogan, J. (1998) “Analysis of incomplete repeated measurements with dependent follow-up times,” Biometrika, 85(1):139– 149.

82. Cheng, C.S., Fine, J. and Wei, L.J. (1998) “Prediction of cumulative incidence function under the proportional hazards model,” Biometrics, 54(1):219-28.

83. Chen, L. and Wei, L.J. (1997) “Analysis of multivariate survival data with non-proportional hazards models,” Proceedings of the First Symposium in Biostatistics: Survival Analysis, Editor: D.Y. Lin and T. Fleming, 23–36.

84. Lin, D.Y., Wei, L.J. and Ying, Z. (1998) “Accelerated failure time models for counting processes,” Biometrika, 85(3)605–618.

85. Fine, J., Ying, Z. and Wei, L.J. (1998) “On the linear transformation models for censored data,” Biometrika, 85(4)980–986.

86. Glidden, D. and Wei, L.J. (1999) “Rank Estimation of Treatment Differences Based on Repeated Measurements Subject to Dependent Censoring,” Journal of the American Statistical Association, 94(447)888–895.

87. Cheng, S.C. and Wei, L.J. (2000) “Inferences for a semi-parametric model with panel data,” Biometrika, 87(1)89–97.

88. Sun, T. and Wei, L.J. (2000) “Regression analysis of panel count data with covariate-dependent observation and censoring times,” Journal of the Royal Statistical Society. Series B, 62(2):293–302.

89. Cai, T. and Wei, L.J. (2000) “Regression analysis for multivariate failure time observations,” Festschrift for George Roussas.

90. Lin, D.Y., Ying, Z. and Wei, L.J. (2001) “Semiparametric transformation models for point processes,” Journal of the American Statistical Association, 96(454):620–628.

91. Cai, T., Wei, L.J. and Wilcox, M (2000) “Semiparametric regression analysis for clustered failure time data,” Biometrika, 87(4)867–878.

92. Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. (2000) “Robust inferences for counting processes under Andersen-Gill model,” Journal of the Royal Statistical Society. Series B, 62(4)711–730.

93. Foster, A.M., Tian, L. and Wei, L.J. (2001) “Estimation for Box-Cox Transformation model without assuming parametric error distribution”, Journal of the American Statistical Association, 96(455):1097–1101.

94. Jin, Z., Ying, Z. and Wei, L.J. (2001) “A simple resampling method by perturbing the minimand,” Biometrika, 88(2):381–390.

95. Lin, D.Y., Wei, L.J. and Ying, Z. (2002) “Model-checking techniques based on cumulative residuals,” Biometrics, 58(1):1-12.

96. Cai, T., Cheng, S.C. and Wei, L.J. (2002) “Semi-parametric mixed effects models for clustered failure time data,” Journal of the American Statistical Association, 97(458):514–522.

97. Gilbert, P., Wei, L.J., Kosorok, M. and Clemens, J. (2002) “Simultaneous inferences on the contrast of two hazard functions with censored observations,” Biometrics, 58(4):773-780.

98. Xu, X., Tian, L. and Wei, L.J. (2003) “Combining dependent tests for linkage or association across multiple phenotypic traits,” Biostatistics, 4(2):223-229.

99. Park Y. and Wei, L.J. (2003) “Estimating subject-specific survival functions under the accelerated failure time model,” Biometrika, 90 (3):717– 723.

100. Jin, Z., Lin, DY, Wei, L.J. and Ying, Z. (2003) “Rank-based inference for the accelerated failure time model,” Biometrika, 90(2):341–353.

101. Tian, L., Wang, W. and Wei, L.J. (2003) “Estimating predictors for long- or short-term survivors,” Biometrics, 59(4):1008-1015.

102. Goldwasser, M.A., Tian, L. and Wei, L.J. (2004) "Statistical inference for infinite dimensional parameters via asymptotically pivotal estimating functions," Biometrika, 91(1):81–94.

103. Tian, L., Liu, Jun, Zhao, Y. and Wei, L.J. (2004) "Statistical inference based on non-smooth estimating functions," Biometrika, 91(4):943–954.

104. Lin M, Wei LJ, Sellers WR, Lieberfarb M, Wong WH, Li C (2004) dChip-SNP : significance curve and clustering of SNP-array-based loss-of-heterozygosity data, Bioinformatics , May 22;20(8):1233-40.

105. Tian, L., Zucker, D. and Wei, L.J. (2005) "On the Cox model with time- varying regression coefficients," Journal of the American Statistical Association, 100(469):172–183.

106. Cai, T., Tian, L. and Wei, L.J. (2005) "Semiparametric Box-Cox power transformation models for censored survival observations," Biometrika, 92(3):619–632.

107. Uno, H., Tian, L., and Wei, L.J. (2005) "The optimal confidence region for a random parameter," Biometrika, 92(4):957–964.

108. Park, Y., Tian, L. and Wei, L.J. (2006) "One- and two-sample nonparametric inference procedures in the presence of a mixture of independent and dependent censoring," Biostatistics, 7(2):252-67.

109. Tian, L., Liu, J. and Wei, L.J. (2007) "Implementation of estimating function based inference procedure with MCMC samplers," Journal of the American Statistical Association (2007 Disucssion paper for JASA theory and method)

110. Tian, L., Cai, T., Goetghebeur, E. and Wei, L.J. (2007) "Model evaluation based on the sampling distribution of estimated absolute prediction error," Biometrika.

111. Uno, H., Cai, T., Tian, L. and Wei, L.J. (2007) "Evaluating prediction rules for t-year survivors with censored regression models", Journal of American Statistical Association.

112. Park, Y., Downing, S. R., Kim, D., Hahn, W. C., Li, C., Kantoff, P. W., and Wei, L.J. (2007). "Simultaneous and exact interval estimates for the contrast of two groups based on an extremely high dimensional variable: application to mass spec data", Bioinformatics, 23(12): 1451-1458.

113. Cai, T., Tian, L. and Wei, L.J. (2008). "Prediction of future observations via working regression models", to appear in Biomtrika.

114. Tian, L., Cai, T., and Wei, L.J. (2008). "Identifying patients who need additional biomarkers for better prediction of health outcome or diagnosis of clinical phenotype", Biometrics.

115. Signorovitch, J. E., and Wei, L.J. (2007). "Wei-Lin-Weissfeld Method for Multiple Times to Events", Wiley Encyclopedia of Clinical Trials.1-3.

116. Leon, L. F., Cai, T., and Wei, L.J. (2009). "Robust inferences for covariate effects on survival time with censored linear regression models", Statistics in Biosciences, 1(1): 50-64.

117. Tian, L., Cai, T., Piankov, N., Cremieux, P. Y., and Wei, L.J. (2009). "Effectively Combining Independent 2 x 2 Tables for Valid Inferences in Meta Analysis with all Available Data but no Artificial Continuity Corrections for Studies with Zero Events and its Application to the Analysis of Rosiglitazone's Cardiovascular Disease Related Event Data", Biostatistics, 10: 275-281.

118. Cai, T., Tian, L., Uno, H., Solomon, S. D., and Wei, L.J. (2010). "Calibrating parametric subject-specific risk estimation", Biometrika, 97(2): 389-404.

119. Wang, R., Tian, L., Cai, T., and Wei, L.J. (2010). "Nonparametric inference procedure for percentiles of the random effects distribution in meta- analysis", The Annals of Applied Statistics, 520-532.

120. Price, A. L., Kryukov, G. V., de Bakker, P. I., Purcell, S. M., Staples, J., Wei, L. J., and Sunyaev, S. R. (2010) "Pooled association tests for rare variants in exon-resequencing studies", The American Journal of Human Genetics, 86(6): 832-838.

121. Uno, H., Cai, T., Pencina, M. J., D'Agostino, R. B., and Wei, L.J. (2011). "On the C-statistics for evaluating overall adequacy of risk prediction procedures with censored survival data", Statistics in medicine, 30(10): 1105- 1117.

122. Li, Y., Tian, L., and Wei, L.J. (2011). "Estimating Subject-Specific Dependent Competing Risk Profile with Censored Event Time Observations", Biometrics, 67(2): 427-435.

123. Cai, T., Tian, L., Wong, P. H., and Wei, L.J. (2011). "Analysis of randomized comparative clinical trial data for personalized treatment selections", Biostatistics, 12(2): 270-282.

124. Uno, H., Cai, T., Tian, L., and Wei, L.J. (2011). "Graphical Procedures for Evaluating Overall and Subject-Specific Incremental Values from New Predictors with Censored Event Time Data", Biometrics, 67(4): 1389- 1396.

125. Tian, L., Wang, R., Cai, T., and Wei, L.J. (2011). "The highest confidence density region and its usage for joint inferences about constrained parameters", Biometrics, 67(2): 604-610.

126. Claggett, B., and Wei, L.J. (2011) "Analytical issues regarding rosiglitazone meta-analysis", Archives of Internal Medicine, 171(2): 179-180.

127. Tian, L., Cai, T., Zhao, L., and Wei, L.J. (2012). "On the covariate- adjusted estimation for an overall treatment difference with data from a randomized comparative clinical trial", Biostatistics, 13(2): 256-273.

128. Zhao, L., Tian, L., Uno, H., Solomon, S. D., Pfeffer, M. A., Schindler, J. S., and Wei, L.J. (2012) "Utilizing the integrated difference of two survival functions to quantify the treatment contrast for designing, monitoring, and analyzing a comparative clinical study", Clinical Trials, 9(5): 570-577.

129. Zhao, L., Tian, L., Cai, T., Claggett, B., and Wei, L.J. (2013). "Effectively selecting a target population for a future comparative study", Journal of the American Statistical Association, 108 (502): 527-539.

130. Cai, T., Tian, L., Lloyd-Jones, D., and Wei, L.J. (2013). "Evaluating subject-level incremental values of new markers for risk classification rule", Lifetime data analysis, 19(4): 547-567.

131. Tian, L., Zhao, L., and Wei, L.J. (2014) "Predicting the restricted mean event time with the subject's baseline covariates in survival analysis", Biostatistics, 15(2): 222-233.

132. Uno, H., Claggett, B., Tian, L., Inoue, E., Gallo, P., Miyata, T., Schrag, D., Takeuchi, M., Uyama, Y., Zhao, L., Skali, H., Solomon, S., Jacobus, S., Hughes, M., Packer, M., and Wei, L.J. (2014) "Moving beyond the hazard ratio in quantifying the between-group difference in survival analysis", Journal of Clinical Oncology, 32(22):2380-2385.

133. Claggett, B., Tian, L., Castagno, D., and Wei, L.J. (2015). "Treatment selections using risk-benefit profiles based on data from comparative randomized clinical trials with multiple endpoints", Biostatistics, 16(1): 60- 72.

134. Uno, H., Wittes, J., Fu, H., Solomon, S.D., Claggett, B., Tian, L., Cai, T., Pfeffer, M.A., Evans, S.R., and Wei, L.J. (2015) "Alternatives to hazard ratios for comparing efficacy or safety of therapies in noninferiority studies", Annals of Internal Medicine, 163(2): 127-134.

135. Uno, H., Tian, L., Claggett, B., and Wei, L.J. (2015). "A versatile test for equality of two survival functions based on weighted differences of Kaplan-Meier curves", Statistics in Medicine, 34(28): 3680-3695.

136. Zhao, L., Claggett, B., Tian, L., Uno, H., Pfeffer, M.A., Solomon, S.D., Trippa, L., and Wei, L.J. (2016). "On the Restricted Mean Survival Time Curve in Survival Analysis", Biometrics, 72(1): 215-221.

137. Li, J., Zhao, L., Tian, L., Cai, T., Claggett, B., Callegaro, A., Dizier, B., Spiessens, B., Ulloa-Montoya, F., and Wei, L.J. (2015). "A predictive enrichment procedure to identify potential responders to a new therapy for randomized, comparative, controlled clinical studies", Biometrics, December 21st, 2015 online first publication.

138. Young F, Tian L, Yu S, Cai T, Wei LJ. (2016). Optimal stratification in outcome prediction using baseline information. Biometrika, 103 (4):817–828.

139. Hasegawa, T., Uno, H., and Wei, L.J. (2016). "Nivolumab in nonsquamous non–small-cell lung cancer", The New England Journal of Medicine, 374: 492-493.

140. Hasegawa, T., Uno, H., and Wei, L.J. (2016). "Neratinib after trastuzumab in patients with HER2-postive breast cancer" The Lancet Oncology, 17: e176.

141. Hasegawa, T., Uno, H., and Wei, L.J. (2016). "How to summarize the safety profile of epoetin alfa versus best standard of care in anemic patients with metastatic breast cancer receiving standard chemotherapy?" Journal of Clinical Oncology, 34 (31):3818.

142. Hasegawa T, Uno H, Wei LJ. (2016). "Safety Study of Salmeterol in Asthma in Adults.", The New England Journal of Medicine, 375 (11):1097.

143. Hasegawa T, Claggett B, Tian L, Solomon S, Pfeffer M, Wei LJ. (2017). "The Myth of Making Inferences for an Overall Treatment Efficacy with Data from Multiple Comparative Studies Via Meta-Analysis." Statistics in Biosciences, 9 (1): 1-14.

144. Cheng D, Pak K, Wei LJ. (2017). "Demonstrating Noninferiority of Accelerated Radiotherapy With Panitumumab vs Standard Radiotherapy With Cisplatin in Locoregionally Advanced Squamous Cell Head and Neck Carcinoma." JAMA Oncology, 3 (10):1430-1431.

145. Horiguchi M, Uno H, Wei LJ. (2017). "Overall Survival in the Randomized Phase II Study Investigating Pazopanib Versus Weekly Paclitaxel in Relapsed or Progressive Urothelial Cancer." Journal of Clinical Oncology, 35 (29):3373.

146. Kim DH, Uno H, Wei LJ. (2017). "Restricted Mean Survival Time as a Measure to Interpret Clinical Trial Results." JAMA Cardiology, 2 (11):1179-1180.

147. Pak K, Uno H, Kim DH, Tian L, Kane RC, Takeuchi M, Fu H, Claggett B, Wei LJ. (2017). "Interpretability of Cancer Clinical Trial Results Using Restricted Mean Survival Time as an Alternative to the Hazard Ratio." JAMA Oncology, 3 (12):1692-1696.

148. Hasegawa T, Uno H, Wei LJ. (2017). "Zoledronic Acid Dosing in Patients With Metastatic Breast Cancer." JAMA Oncology, 4 (4):585.

149. Tian L, Fu H, Ruberg SJ, Uno H, Wei LJ. (2017). "Efficiency of two sample tests via the restricted mean survival time for analyzing event time observations." Biometrics, 74 (2):694-702.

150. Tian L, Jiang F, Hasegawa T, Uno H, Pfeffer M, Wei LJ. (2018). "Moving beyond the conventional stratified analysis to estimate an overall treatment efficacy with the data from a comparative randomized clinical study." Statistics in Medicine, doi: 10.1002/sim.8015.

151. Jiang F, Tian L, Fu H, Hasegawa T, Wei LJ. (2018). "Robust alternatives to ANCOVA for estimating the treatment effect via a randomized comparative study." Journal of the American Statistical Association, doi: 10.1080/01621459.2018.1527226.

152. Angelidou K, Palumbo P, Lindsey J, Violary A, Archary M, Barlow L, Claggett B, Hughes M, Wei LJ; International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT) P1060 Study Team. (2018). "Defining Study Outcomes That Better Reflect Individual Response to Treatment." Pediatric Infectious Disease Journal, 37 (3):258-262.

153. Horiguchi M, Uno H, Wei LJ. (2018). "Patients With Advanced Melanoma Who Discontinued Treatment With Nivolumab and Ipilimumab as a Result of Adverse Events Lived Significantly Longer Than Patients Who Continued Treatment." Journal of Clinical Oncology, 36 (7):720-721.

154. Uno H, Hassett MJ, Wei LJ. (2018). "Axillary vs Sentinel Lymph Node Dissection in Women With Invasive Breast Cancer." JAMA, 319 (3):306.

155. Fang X, Uno H, Wei LJ. (2018) "Assessing Metronomic Chemotherapy for Progressive Pediatric Solid Malignant Tumors." JAMA Oncology, 4 (5):743.

156. Horiguchi M, Uno H1 Wei LJ. (2018). "Evaluating Noninferiority With Clinically Interpretable Statistics for the PROSELICA Study to Assess Treatment Efficacy of a Reduced Dose of Cabazitaxel for Treating Metastatic Prostate Cancer." Journal of Clinical Oncology, 36 (8):825-826.

157. Zhao L, Tian L, Claggett B, Pfeffer M, Kim DH, Solomon S, Wei LJ. (2018). "Estimating Treatment Effect With Clinical Interpretation From a Comparative Clinical Trial With an End Point Subject to Competing Risks." JAMA Cardiology, 3 (4):357-358.

158. Sun R, Horiguchi M, Wei LJ. (2018). "Interpreting the Benefit of Trifluridine/Tipiracil in Metastatic Colorectal Cancer With Respect to Progression-Free Survival and Overall Survival." Journal of Clinical Oncology, 36 (13):1378-1379.

159. Huang B, Tian L, Talukder E, Rothenberg M, Kim DH, Wei LJ. (2018). "Evaluating Treatment Effect Based on Duration of Response for a Comparative Oncology Study." JAMA Oncology, 4 (6):874-876.

160. Horiguchi M, Tian L, Uno H, Cheng S, Kim DH, Schrag D, Wei LJ. (2018). "Quantification of Long-term Survival Benefit in a Comparative Oncology Clinical Study." JAMA Oncology, 4 (6):881-882.

161. Uno H, Kim DH, Wei LJ. (2018). "Interpreting the Association of First-in-Class Immune Checkpoint Inhibition and Targeted Therapy With Survival in Patients With Stage IV Melanoma." JAMA Oncology, 4 (8):1135-1136.

162. Uno H, Tian L, Wei LJ (2018). "Estimating and Interpreting the Overall Survival Benefit of Checkpoint Inhibitors via Meta-analysis." JAMA Oncology, 4 (8):1137-1138.

163. Claggett B, Tian L, Fu H, Solomon SD, Wei LJ. (2018) "Quantifying the totality of treatment effect with multiple event-time observations in the presence of a terminal event from a comparative clinical study." Statistics in Medicine, 37 (25):3589-3598.

164. Claggett B, Tian L, McCaw ZR, Takeuchi M, Wei LJ. (2018). "Sex as a predictor of response to cancer immunotherapy." The Lancet Oncology, 19 (8):e377.

165. McCaw ZR, Orkaby AR, Wei LJ, Kim DH, Rich MW. (2018). "Applying Evidence-Based Medicine to Shared Decision Making: Value of Restricted Mean Survival Time." American Journal of Medicine, (18) 30750-2.

166. Claggett B, Tian L, Wei LJ. (2018) "Meta-analysis to Evaluate High-Dose Therapy Followed by Stem Cell Transplant in Patients With Multiple Myeloma." JAMA Oncology, 4 (11):1617-1618.

167. Orkaby AR, Rich MW, Sun R, Lux E, Wei LJ, Kim DH. (2018). "Pravastatin for Primary Prevention in Older Adults: Restricted Mean Survival Time Analysis." Journal of the American Geriatric Society, 66 (10):1987-1991.

168. Sun R, Rich MW, Wei LJ. (2018). "Pembrolizumab plus Chemotherapy in Lung Cancer." The New England Journal of Medicine, 379 (11):e18.

169. McCaw ZR, Wei LJ, Kim DH. (2018). “Gene Expression-Guided Adjuvant Chemotherapy in Breast Cancer.” The New England Journal of Medicine, 379 (17):1681.

170. Sun R, Nie L, Huang B, Kim DH, Wei LJ. (2018). “Quantifying Immunoscore performance.” The Lancet, 392 (10158):1624.

171. McCaw ZR, Tian L, Kim DH, Wei LJ. (2018). “Interpreting Clinical Benefits of Neoadjuvant Chemoradiation With Gemcitabine Versus Upfront Surgery in Patients With Borderline Resectable Pancreatic Cancer (BRPC).” Annals of Surgery, doi: 10.1097/SLA.0000000000003115.

172. Sun R, Lee H, Wei LJ. (2018). “Interpreting the Long-term Prognostic Value of Total Mesorectal Excision Plane Quality in Rectal Adenocarcinoma.” JAMA Surgery, doi: 10.1001/jamasurg.2018.3540.

173. McCaw ZR, Liu D, Wei LJ. (2018). “Body Composition and Overall Survival in Patients With Nonmetastatic Breast Cancer.” JAMA Oncology, doi: 10.1001/jamaoncol.2018.5290.

174. McCaw ZR, Piantadosi S, Wei LJ. (2018). “Quantifying the Added Value of Low-Molecular-Weight Heparin to Intermittent Pneumatic Compression for Preventing Venous Thromboembolic Events Under the Risk-Benefit Perspective.” JAMA Surgery, doi: 10.1001/jamasurg.2018.4294.

175. Sun R, Wei LJ. (2018). “Regional Hyperthermia With Neoadjuvant Chemotherapy for Treatment of Soft Tissue Sarcoma.” JAMA Oncology, doi: 10.1001/jamaoncol.2018.5287.

176. Farlow MR, Thompson RE, Wei LJ, Tuchman AJ, Grenier E, Crockford D, Wilke S, Benison J, Alkon DL. (2018). “A Randomized, Double-Blind, Placebo-Controlled, Phase II Study Assessing Safety, Tolerability, and Efficacy of Bryostatin in the Treatment of Moderately Severe to Severe Alzheimer's Disease.” Journal of Alzheimer’s Disease, doi: 10.3233/JAD-180759.

177. McCaw ZR, Jiang F, Wei LJ. (2018). “Trastuzumab Therapy for 9 Weeks vs 1 Year for Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer.” JAMA Oncology, doi: 10.1001/jamaoncol.2018.5730.

178. Sun R, Zhu H, Wei LJ. (2018). “Assessing the Prognostic Value of the Automated Bone Scan Index for Prostate Cancer.” JAMA Oncology, doi: 10.1001/jamaoncol.2018.5857.

179. McCaw ZR, Kim DH, Tian L, Fu H, Wei LJ. (2019). “Trifluridine/tipiracil in metastatic gastric cancer.” The Lancet Oncology, doi: 10.1016/S1470-2045(18)30908-2.

180. McCaw ZR, Kim DH, Wei LJ. (2019). “Evaluating Treatment Effect of Transcatheter Interatrial Shunt Device Using Heart Failure Event Rates.” JAMA Cardiology. 4(3):299 doi: 10.1001/jamacardio.2019.0001.

181. Claggett B, Uno H, Wei LJ. (2019). “Unifying Design and Analysis for Superiority and Noninferiority Trials With Appropriate End Point.” JAMA Surgery. 154(5):466-467. doi: 10.1001/jamasurg.2018.5852.

182. McCaw ZR, Vassy JL, Wei LJ.(2019). "Palbociclib and Fulvestrant in Breast Cancer." The New England Journal of Medicine. 380(8):796. doi: 10.1056/NEJMc1816595.

183. McCaw ZR, Wei LJ, Kim DH. (2019). "Interpreting the Prognostic Value of Unrecognized Myocardial Infarction Among Older Adults." JAMA Cardiology. 4(4):391. doi: 10.1001/jamacardio.2019.0184.

184. Zemplenyi M, Wei LJ. (2019). "Quantifying the Treatment Effect of Drug-Eluting Stents Optimized for Biocompatibility vs Bare-Metal Stents With a Single Month of Dual Antiplatelet Therapy." JAMA Cardiology. 4(5):494. doi: 10.1001/jamacardio.2019.0546.

185. McCaw ZR, Wei LJ, Kim DH. (2019). "Effects of Aspirin in the Healthy Elderly." The New England Journal of Medicine. 380(18):1775-1776. doi: 10.1056/NEJMc1901774.

186. Wei LJ, Sun R, Orkaby AR, Kim DH, Zhu H. (2019). "Biodegradable-polymer stents versus durable-polymer stents." The Lancet. 393(10184):1932-1933. doi: 10.1016/S0140-6736(19)30023-6

187. Torbicki A, Bacchi M, Delcroix M, Farber HW, Ghofrani HA, Hennessy B, Jansa P, Mehta S, Perchenet L, Pulido T, Rosenberg D, Rubin LJ, Sastry BKS, Simonneau G, Sitbon O, Souza R, Wei LJ, Channick R, Benza R. (2019). "Integrating Data From Randomized Controlled Trials and Observational Studies to Assess Survival in Rare Diseases." Circ Cardiovasc Qual Outcomes. 12(5):e005095. doi: 10.1161/CIRCOUTCOMES.118.005095.

188. McCaw ZR, Kim DH, Wei LJ. (2019). "Analysis of Long-term Benefits of Intensive Blood Pressure Control." JAMA. 322(2):169-170. doi: 10.1001/jama.2019.5840.

189. Manner DH, Battioui C, Hantel S, Beasley BN, Wei LJ, Geiger MJ, Turner JR, Abt M. (2019). "Restricted mean survival time for the analysis of cardiovascular outcome trials assessing non-inferiority: Case studies from antihyperglycemic drug development." American Heart Journal. 215:178-186. doi: 10.1016/j.ahj.2019.05.016.

190. McCaw ZR, Meng Z, Wei LJ. (2019). "A Shorter Regimen for Rifampin-Resistant Tuberculosis." The New England Journal of Medicine.12;381(11):e22. doi: 10.1056/NEJMc1905782.

191. Rabideau DJ, Kim DH, Wei LJ. (2019). "Using Confidence Intervals to Quantify Statistical and Clinical Evidence for the Treatment Effect in a Comparative Study-Moving Beyond P Values." JAMA Otolaryngology Head Neck Surgery. doi: 10.1001/jamaoto.2019.3057.

192. McCaw ZR, Yin G, Wei LJ. (2019). "Using the Restricted Mean Survival Time Difference as an Alternative to the Hazard Ratio for Analyzing Clinical Cardiovascular Studies." Circulation. 140(17):1366-1368. doi: 10.1161/CIRCULATIONAHA.119.040680.

193. McCaw ZR, Wei LJ. (2019). "P2Y12 Inhibitor Monotherapy vs Dual Antiplatelet Therapy After Percutaneous Coronary Intervention." JAMA. 322(16):1607. doi: 10.1001/jama.2019.13159.

194. Ludmir EB, McCaw ZR, Grossberg AJ, Wei LJ, Fuller CD. (2019). "Quantifying the benefit of non-small-cell lung cancer immunotherapy." The Lancet. 394(10212):1904. doi: 10.1016/S0140-6736(19)32503-6.

195. Li D, McCaw ZR, Wei LJ. (2020). "Interpreting the Benefit of Simvastatin-Ezetimibe in Patients 75 Years or Older." JAMA Cardiol. 2020 Jan 2. doi: 10.1001/jamacardio.2019.5200.

196. Li D, McDonald CM, Elfring GL, Souza M, McIntosh J, Kim DH, Wei LJ. (2020). "Assessment of Treatment Effect With Multiple Outcomes in 2 Clinical Trials of Patients With Duchenne Muscular Dystrophy." JAMA Netw Open. 2020 Feb 5;3(2):e1921306. doi: 10.1001/jamanetworkopen.2019.21306.

197. Tian L, Jin H, Uno H, Lu Y, Huang B, Anderson KM, Wei LJ. (2020). "On the empirical choice of the time window for restricted mean survival time." Biometrics. 2020 Feb 15. doi: 10.1111/biom.13237.

198. McCaw ZR, Wei LJ, Ludmir EB. (2020). "Interpreting the impact of apalutamide on overall survival among patients with non-metastatic castration-resistant prostate cancer." Ann Oncol. 2020 Mar;31(3):438-440. doi: 10.1016/j.annonc.2019.11.020.

199. Huang B, Wei LJ, Ludir EB. (2020) "Estimating Treatment Effect as the Primary Analysis in a Comparative Study: Moving Beyond P Value." J Clin Oncol. 2020 Jun 10;38(17):2001-2002. doi: 10.1200/JCO.19.03111.

200. Ludmir EB, McCaw ZR, Kim DH, Tian L, Wei LJ. (2020) "Fulvestrant plus capivasertib for metastatic breast cancer". Lancet Oncol. 2020 May;21(5):e233. doi: 10.1016/S1470-2045(20)30228-X.

201. Sun R, Kim DH, Wei LJ. (2020) "Analysis of Overall Survival Benefit of Abemaciclib Plus Fulvestrant in Hormone Receptor-Positive, ERBB2-Negative Breast Cancer." JAMA Oncol 2020 Jul 1;6(7):1121-1122. doi: 10.1001/jamaoncol.2020.1513.

202. McCaw ZR, Kim DH, Wei LJ. (2020) "Risk-Benefit Comparisons Between Shorter and Longer Durations of Adjuvant Chemotherapy in High-Risk Stage II Colorectal Cancer." JAMA Oncol. 2020 Aug 1;6(8):1301-1302. doi: 10.1001/jamaoncol.2020.2256.

203. McCaw ZR, Tian L, Vassy JL, Ritchie CS, Lee CC, Kim DH, Wei LJ. (2020) "How to Quantify and Interpret Treatment Effects in Comparative Clinical Studies of COVID-19." Ann Intern Med. 2020 Jul 7:M20-4044. doi: 10.7326/M20-4044.

204. McCaw ZR, Ludmir EB, Kim DH, Wei LJ. (2020) "Further clinical interpretation and implications of KEYNOTE-048 findings." Lancet. 2020 Aug 8;396(10248):378-379. doi: 10.1016/S0140-6736(20)30904-1.

205. Campbell C, Barohn RJ, Bertini E, Chabrol B, Comi GP, et al. (2020) "Meta-analyses of ataluren randomized controlled trials in nonsense mutation Duchenne muscular dystrophy." J Comp Eff Res. 2020 Aug 27. doi: 10.2217/cer-2020-0095.

206. Huang B, Tian L, McCaw ZR, Luo X, Talukder E, Rothenberg M, Xie W, Choueiri TK, Kim DH, Wei LJ. (2020) "Analysis of Response Data for

Assessing Treatment Effects in Comparative Clinical Studies." Ann Intern Med. 2020 Sep 1;173(5):368-374. doi: 10.7326/M20-0104.

207. McCaw ZR, Kim DH, Wei LJ. (2020) " Remdesivir for the Treatment of Covid-19 - Preliminary Report." N Engl J Med. 2020 Sep 3;383(10):993. doi: 10.1056/NEJMc2022236.

208. McCaw ZR, Tian L, Sheth KN, Hsu WT, Kimberly WT, Wei LJ. (2020) "Selecting appropriate endpoints for assessing treatment effects in comparative clinical studies for COVID-19." Contemp Clin Trials. 2020 Sep 12;97:106145. doi: 10.1016/j.cct.2020.106145.

209. McCaw ZR, Tian L, Wei LJ. (2020) "Appropriate Analysis of Duration of Response Data in Cancer Trials." JAMA Oncol. 2020 Oct 8. doi: 10.1001/jamaoncol.2020.4657.

210. Perego C, Sbolli M, Specchia C, Fiuzat M, McCaw ZR, Metra M, Oriecuia C, Peveri G, Wei LJ, O'Connor CM, Psotka MA. (2020) "Utility of Restricted Mean Survival Time Analysis for Heart Failure Clinical Trial Evaluation and Interpretation." JACC Heart Fail. 2020 Dec;8(12):973-983. doi: 10.1016/j.jchf.2020.07.005.

211. McCaw ZR, Tian L, Kim DH, Localio AR, Wei LJ. (2020) "Survival analysis of treatment efficacy in comparative COVID-19 studies." Clin Infect Dis. 2020 Oct 14:ciaa1563. doi: 10.1093/cid/ciaa1563.

212. Sun R, Messick C, Wei LJ. (2020) "Two-Stage Turnbull-Cutait Pull-Through Coloanal Anastomosis for Low Rectal Cancers." JAMA Surg. 2020 Nov 11. doi: 10.1001/jamasurg.2020.5189.

213. Shi S, Wei LJ, Kim DH. (2020) Restricted Mean Survival Time in Action to Control Cardiovascular Risk in Diabetes (ACCORD) Blood Pressure. Innov Aging. 2020 Dec 16. doi: 10.1093/geroni/igaa057.1588.

214. Ludmir EB, McCaw ZR, Wei LJ. (2020) "Final Analysis of the Ipilimumab Versus Placebo Following Radiotherapy Phase III Trial in Postdocetaxel Metastatic Castration-resistant Prostate Cancer Identifies an Excess of Long-term Survivors." Eur Urol. 2021 Jan;79(1):e10-e11. doi: 10.1016/j.eururo.2020.09.049.

215. McCaw ZR, Fitzmaurice G, Wei LJ. "The COMPASS Trial: Net Clinical Benefit of Low-Dose Rivaroxaban Plus Aspirin as Compared With Aspirin in Patients With Chronic Vascular Disease." Circulation. 2021 Jan 5;143(1):e1-e2. doi: 10.1161/CIRCULATIONAHA.120.050723.

STATISTICAL APPLICATION PUBLICATIONS

216. Rock MJ, Mischler EH, Farrell PM, Wei LJ, Bruns WT, Hassemer DJ, Laessig RH. (1990) Newborn screening for cystic fibrosis is complicated by age-related decline in immunoreactive trypsinogen levels, Pediatrics, Jun;85(6):1001-7.

217. Van Why SK, Friedman AL, Wei LJ, Hong R. (1991) Renal insufficiency after bone marrow transplantation in children, Bone Marrow Transplant; 7(5):383-8.

218. Rogus JJ, Cai T, Wei LJ. (1999) Issues in genomic screening: critical values, sample sizes, and the ability to detect linkage, Genet Epidemiol., 17 Suppl 1:S697-701.

219. Eshleman SH, Krogstad P, Jackson JB, Wang YG, Lee S, Wei LJ, Cunningham S, Wantman M, Wiznia A, Johnson G, Nachman S, Palumbo P. (2001) Analysis of human immunodeficiency virus type 1 drug resistance in children receiving nucleoside analogue reverse-transcriptase inhibitors plus nevirapine, nelfinavir, or ritonavir (Pediatric AIDS Clinical Trials Group 377), J Infect Dis., Jun 15;183(12):1732-8 .

220. Mutter GL, Baak JP, Fitzgerald JT, Gray R, Neuberg D, Kust GA, Gen- tleman R, Gullans SR, Wei LJ, Wilcox M (2001) Global expression changes of constitutive and hormonally regulated genes during endometrial neo- plastic transformation, Gynecol Oncol., Nov;83(2):177-85.

221. Xu X, Palmer LJ, Horvath S, Wei LJ (2001) Combining multiple phe- notypic traits optimally for detecting linkage with sib-pair observations, Genet Epidemiol., 21 Suppl 1:S479-83.

222. Chuang SK, Tian L, Wei LJ, Dodson TB (2001) Kaplan-Meier analysis of dental implant survival: a strategy for estimating survival with clustered observations, J Dent Res., Nov;80(11):2016-20.

223. Chuang SK, Tian L, Wei LJ, Dodson TB (2002) Predicting dental implant survival by use of the marginal approach of the semi-parametric survival methods for clustered observations, J Dent Res., Dec;81(12):851-5.

224. Chuang SK, Wei LJ, Douglass CW, Dodson TB (2002) Risk factors for dental implant failure: a strategy for the analysis of clustered failure-time observations, J Dent Res., Aug;81(8):572-7.

225. Wei E, Wei LJ, Xu X (2003) A simple nonparametric test for linkage with sib-pair censored event time observations, Hum Hered., 55(2-3):143-6.

226. Hitti J, Frenkel LM, Stek AM, Nachman SA, Baker D, Gonzalez-Garcia A, Provisor A, Thorpe EM, Paul ME, Foca M, Gandia J, Huang S, Wei LJ, Stevens LM, Watts DH, McNamara J; PACTG 1022 Study Team (2004) Maternal toxicity with continuous nevirapine in pregnancy: results from PACTG 1022, J Acquir Immune Defic Syndr., Jul 1;36(3):772-6.

227. Wang ZC, Lin M, Wei LJ, Li C, Miron A, Lodeiro G, Harris L, Ramaswamy S, Tanenbaum DM, Meyerson M, Iglehart JD, Richardson A (2004) Re- lated Articles, Links Loss of heterozygosity and its correlation with expression profiles in subclasses of invasive breast cancers, Cancer Res., Jan 1;64(1):64-71.

228. Chuang SK, Cai T, Douglass CW, Wei LJ, Dodson TB (2005) Related Articles, Links Frailty approach for the analysis of clustered failure time observations in dental research, J Dent Res., Jan;84(1):54-8.

229. Hughes WT, Dankner WM, Yogev R, Huang S, Paul ME, Flores MA, Kline MW, Wei LJ, Pediatric AIDS Clinical Trials Group 254 Team (2005) Comparison of atovaquone and azithromycin with trimethoprim-sulfamethoxazole for the prevention of serious bacterial infections in children with HIV in- fection, Clin Infect Dis., Jan 1;40(1):136-45.

230. Wang L, Feng Y, Zhang Y, Zhou H, Jiang S, Niu T, Wei LJ, Xu X, Xu X, Wang X. (2006) Prolylcarboxypeptidase gene, chronic hypertension, and risk of preeclampsia , Am J Obstet Gynecol, Jul;195(1):162-71.

231. Zhou, H., Wei, L. J., and Xu, X. (2007) Combining association tests across multiple genetic markers in case-control studies. Human heredity, 65(3): 166-174.

232. Dienstag JL, Wei LJ, Xu D, Kreter B. (2007) Cross-study analysis of the relative efficacies of oral antiviral therapies for chronic hepatitis B infection in nucleoside-naive patients, Clin Drug Investig, 27(1):35-49.

233. Elkayam, U., Janmohamed, M., Hatamizadeh, P., Heywood, J. T., Wei, L. J., and Mills, R. M. (2009) Impact of acute serum creatinine elevation in patients treated with nesiritide. Clinical cardiology, 32(4): 215-219.

WEI

EXHIBIT B

In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 19-2875

LEE-JEN WEI, PHD
LIST OF MATERIALS CONSIDERED

MATERIALS CONSIDERED	BATES NOS.
MDL PLEADINGS AND GENERAL DOCUMENTS	
2019.06.17 Am. Master Personal Injury Complaint	N/A
2019.06.17 Am. Master Medical Monitoring Complaint	N/A
2020.03.13 Am. Master Economic Monitoring Complaint	N/A
2019.06.26 Confidentiality and Protective Order	N/A
2021.02.11 Letter from Lori G. Cohen to Judge Vanaskie	N/A
2021.02.11 Letter from Adam Slater Providing an Overview	N/A
EXPERT REPORTS (WITH EXHIBITS)	
2021.07.04 Report of Dr. Mahyar Etminan	N/A
2021.07.06 Report of Dr. Stephen Hecht	N/A
2021.07.06 Report of Dr. Stephen Lagana	N/A
2021.07.07 Report of Dr. David Madigan	N/A
2021.07.06 Report of Dr. Dipak Panigrahy	N/A
DISCOVERY DOCUMENTS CITED BY PLAINTIFFS' EXPERTS	
Spreadsheet of NDMA Test Results for ZHP API	SOLCO00028261
Torrent Pharmaceutical Limited – Valsartan Impact Assessment of NDMA	TORRENT-MDL2875-00133890
LITERATURE	
2017.11.00 EPA NDMA Technical Fact Sheet	N/A
All materials cited in the 2021.07.04 Report of Dr. Mahyar Etminan	N/A
All materials cited in the 2021.07.04 Report of Dr. Stephen Hecht	N/A
All materials cited in the 2021.07.04 Report of Dr. Stephen Lagana	N/A
All materials cited in the 2021.07.04 Report of Dr. David Madigan	N/A
All materials cited in the 2021.07.04 Report of Dr. Dipak Panigrahy	N/A
De Stefani, E, Galer, D. M., Leung, H. W., Sussman, R. G., & Trzos, R. J. (1992). Scientific and practical considerations for the development of occupational exposure limits (OELs) for chemical substances. Regulatory Toxicology and Pharmacology, 15(3), 291-306	N/A
EPA, High-fat foods and the risk of lung cancer. Epidemiology 1992; 3:288-99	N/A
FDA, Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer. Cancer Epidemiol Biomarkers Prev 1995; 4(1):29-36	N/A
FDA, Dietary nitrosodimethylamine and the risk of lung cancer: a case-control study from Uruguay. Cancer Epidemiol Biomarkers Prev 1996; 5(9):679-82	N/A

MATERIALS CONSIDERED	BATES NOS.
Friedman, Furberg and DeMets, Fundamentals of Clinical Trials, Second Edition, Chapter 15; p. 215, Littleton, MA, 1985	N/A
Galer, DM, et al., Risk of colorectal and other gastro-intestinal cancers after exposure to nitrate, nitrite and N-nitroso compounds: a follow up study. Int J Cancer 1999; 80:852-56	N/A
Gomm, W., et al., "N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer – A Longitudinal Cohort Study Based on German Health Insurance Data," PubMed Abstract (2021)	N/A
Gomm, W., et al., "N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer – A Longitudinal Cohort Study Based on German Health Insurance Data," English version (2021)	N/A
Goodman, MT, et al., N-Nitrosodimethylamine - Hazard Summary (2000)	N/A
Hidajat, M., et al: Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow-up. Occup. Environ. Med. 76:250-258, 2019	N/A
IARC. (1978). Some N-Nitroso Compounds. Retrieved from Lyon, France	N/A
IARC (International Agency for Research on Cancer), 25 Kipnis, V., Subar, A. F., Midthune, D., Freedman, L. S., Ballard-Barbash, R., Troiano, R. P., & Carroll, R. J. (2003). Structure of dietary measurement error: results of the OPEN biomarker study. American Journal of Epidemiology, 158(1), 14-21	N/A
Jakszyn, P, et al., Red meat, dietary nitrosamines, and heme iron and risk of bladder cancer in the European prospective investigation into cancer and nutrition (EPIC). Cancer Epidemiol Biomarkers Prev 2011; 20(3):555-59	N/A
Johnson, GE, et al., Nitrosamines and heme iron and risk of prostate cancer in the European prospective investigation into cancer and nutrition. Cancer Epidemiol Biomarkers Prev 2012; 21(3):547-51	N/A
Knekt, P., et al, "Risk of Colorectal and Other Gastro-Intestinal Cancers After Exposure to Nitrate, Nitrite and N-Nitroso Compounds: A Follow-Up Study," Int. J. Cancer (1999)	N/A
Larsson, S., et al, "Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women," Int. J. Cancer (2006)	N/A
Loh, Y., et al, "N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC) – Norfolk Study," Am. Society for Nutrition (2011)	N/A
Madigan, D., et al., A systematic statistical approach to evaluating evidence from observational studies. Annual Review of Statistics and Its Application, 1, 11-39	N/A
McCaw et al., How to Quantify and Interpret Treatment Effects in Comparative	N/A

MATERIALS CONSIDERED	BATES NOS.
Clinical Studies of COVID-19, (2020) Ann Intern Medicine, doi:10.7326/M20-4044	
McCaw, Zack, Kim, Dae and Lee-Jen Wei, Letter to the Editor for Remdesivir for the Treatment of Covid-19— Preliminary Report, New England Journal of Medicine (2020). DOI: 10.1056/NEJMc2022236	N/A
Pak, et al. Interpretability of Cancer Clinical Trial Results Using Restricted Mean Survival Time as an Alternative to the Hazard Ratio (2017) JAMA Oncol. Doi:10.1001/jamaoncol.2017.2797	N/A
Pottegard, A., et al, "Use of N-Nitrosodimethylamine (NDMA) contaminated Valsartan products and risk of cancer: Danish nationwide cohort study," (2018)	N/A
Rogers, MAM, et al., Laboratory analysis of valsartan products (2019)	N/A
Snodin, DJ, et al., Short commentary on NDMA (N-nitrosodimethylamine) contamination of Valsartan products. Regulatory Toxicology and Pharmacology 103:325-329 (2019)	N/A
Song, P., et al, "Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric-Cancer: A Meta-Analysis," Nutrients (2015)	N/A
Uno et al. Moving Beyond the Hazard Ratio in Quantifying the Between-Group Difference in Survival Analysis, Journal of Clinical Oncology (2014) DOI: 10.1200/JCO.2014.55.2208	N/A
Wasserstein, Ronald L. & Lazar, Nicole A. (2016) The ASA Statement on p-Values: Context, Process, and Purpose, *The American Statistician*, 70:2, 129-133, DOI: 10.1080/00031305.2016.1154108	N/A
Zhao L, Tian L, Claggett B, et al. Estimating treatment effect with clinical interpretation from a comparative clinical trial with an end point subject to competing risks. JAMA Cardiol (2018); 3: 357-8	N/A
Zheng, J, et al., Permitted daily exposure limits for noteworthy N-nitrosamines. Environmental and Molecular Mutagenesis (07 May 2021)	N/A
Zheng J, Stuff J, Tang H, Hassan MM, Daniel CR, Li D. Dietary N-nitroso compounds and risk of pancreatic cancer: results from a large case-control study. Carcinogenesis 2019; 40(2):254-62	N/A
Zhu, Y, et al., Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada. Brit J Nutrition 2014;111:1109-1117	N/A
MISCELLANEOUS	
All materials cited or referenced in my expert report and attachments	N/A
This list includes items Plaintiffs' experts relied upon. By so doing, Defendants and this expert are not waiving any arguments or objections related to admissibility.	N/A